

Type: Poster Presentation

Final Abstract Number: 43.152
 Session: Poster Session III
 Date: Saturday, March 5, 2016
 Time: 12:45–14:15
 Room: Hall 3 (Posters & Exhibition)

A quick method to determine the best threshold level for universal vaccination when there is an outbreak of Japanese Encephalitis

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Background: Japanese Encephalitis (JE) has an increasing trend in many parts of the world, especially the global warming facilitates the perpetuation of the vectors, mosquitoes. Although JE vaccination is a proven useful control strategy, at the same time it has a not low associated complication rate. What is the best time to opt for universal vaccination need a careful balance.

Methods & Materials: A risk versus benefit approach is used to determine the best time to opt for universal JE vaccination, using Hong Kong as an example. Two sources of information are used to determine the case loads / endemicity of JE (as a proxy to estimate the potential benefit for vaccination): (1) Seroprevalence in different population subgroups; (2) Surveillance information from the Government Disease Control Centre under the WHO IHR. Two sources of information are used to assess the potential risks for vaccination: (1) Complication rate for JE vaccination based on pharmaceutical companies' data; (2) Acceptability, knowledge and attitude of JE vaccination in the public

Results: The baseline case load of JE in Hong Kong is not high. However, certain subgroups are at high risk (e.g. elderly) as reflected by a higher seroprevalence rate. Universal vaccination may be justified only if the annual incidence is higher than the damage potentially caused by the vaccination itself.

Conclusion: There is a need to review the surveillance process since updated data is the crux for an accurate assessment. Even if there is an universal JE vaccination program, the responsible authority (e.g. government) has to address the concern from the public in order to achieve a satisfactory coverage for significant community protection.

<http://dx.doi.org/10.1016/j.ijid.2016.02.889>

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Clinical Review of Shanchol™ (a WHO pre-qualified oral cholera vaccine)

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Background: Cholera caused by *Vibrio cholerae* of the O1 or O139 serogroup is an important cause of severe dehydrating diarrhea in adults and children. It continues to be a major global health problem. The WHO estimates that 3–5 million cases and 100,000–130,000 deaths occur per year globally, predominantly in Asia and Africa.

The WHO recommends that in cholera-endemic countries, vaccination should be used as an additional tool to control cholera along with longer term interventions of improving water and sanitation. It recommends pre-emptive vaccination to help prevent potential outbreaks or the spread of current outbreaks.

Shanchol™ is a ready-to-use killed bivalent (O1 and O139) whole-cell oral cholera vaccine administered as 2 doses 14 days apart in individuals aged 1 year and above. There is no need for buffer or water for its administration. It is currently licensed in India and 17 other countries in Asia, Africa and Latin America. It is prequalified for international use by the WHO. The vaccine is the basis for the WHO stockpile which is used to help control cholera epidemics.

Methods & Materials: Clinical analysis of safety, immunogenicity and efficacy studies of Shanchol™

Results: Overall, ~66,000 doses have been administered to subjects during the clinical development of the vaccine. Shanchol™ was observed to provide sustained protective efficacy level of 65% for at least 5 years in a clinical trial conducted in over 69,000 subjects in India. The herd effect conferred by Shanchol™ was evident with minimum vaccine coverage of 38% and was sustained for at least 3 years.

Safety and immunogenicity clinical trials conducted in India, Bangladesh, Ethiopia, Philippines and Haiti showed that the vaccine is safe and provides good immune responses in different endemic populations.

Results from a clinical study showed that flexible dosing schedule of Shanchol™ as 2 doses 14 to 28 days apart is possible. A modeling study observed that single-dose vaccination may prevent more deaths during outbreaks than 2-dose vaccination.

Shanchol™ was also observed to be highly effective in mass vaccination campaigns in Guinea, Haiti, Odisha (India) and Bangladesh.

Conclusion: Shanchol™ vaccine is **safe and effective for control of cholera** in endemic countries

<http://dx.doi.org/10.1016/j.ijid.2016.02.890>